

AUG 29 2008

Premarket Notification 510(k) Summary  
As required by section 807.92  
GE Datex-Ohmeda Avance

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

**COMPANY NAME/ADDRESS/PHONE/FAX:**

Datex-Ohmeda, Inc.  
PO Box 7550  
Madison, WI 53707 USA  
Tel: 608-221-1551  
Fax: 608-223-2496

**NAME OF CONTACT:**

Ms. Adrienne Lenz, RAC  
Ms. Karla Krause (alternate)

**DATE:**

June 25, 2008

**DEVICE NAME as required by 807.92(a)(2)**

**TRADE NAME:**

GE Datex-Ohmeda Avance

**COMMON NAME:**

Gas Machine, Anesthesia

**CLASSIFICATION NAME:**

Anesthesiology, 73 BSZ, 21 CFR 868.5160 Gas Machine, Anesthesia

**NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)**

The GE Datex-Ohmeda Avance is substantially equivalent in safety and effectiveness to the legally marketed (predicate) GE Datex-Ohmeda Avance (K071142) and the GE Datex-Ohmeda Aisys (K073707).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The GE Datex-Ohmeda Avance is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. It represents one of the systems in a long line of products based on the Datex-Ohmeda Excel, Aestiva, Aespire, and Aisys Anesthesia Systems. It is to be used only by trained and qualified medical professionals.

The Datex-Ohmeda Avance Anesthesia System supplies set flows of medical gases to the breathing system using electronic gas mixing. Gas flows are selected by the user using the keypad and rotary controller on the main display unit and then displayed as electronic flow meters on the system display unit. The Avance is equipped with a pneumatic back-up O<sub>2</sub> delivery system and traditional flow tube, as well. A large selection of frames, gases, and vaporizers are available to give the user control of the system configuration. The Avance is also available in wall-mount and pendant models. It is available with two or three gases, up to two vaporizer positions and up to three cylinder connections. All models have O<sub>2</sub>. The Avance comes with up to two optional gases (air, N<sub>2</sub>O).

The Avance systems accept Tec 4, Tec 5, Tec 6, and Tec 7 vaporizers on a Selectatec manifold. Safety features and devices within the Avance are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Avance system is available with optional integrated respiratory gas monitoring. When supplied as an option, the integrated respiratory gas monitoring is provided via the Datex-Ohmeda M-Gas Module (M-CAiO and M-CAiOV software revision 3.2 and above K# 001814) which is physically integrated into the Avance, receives electronic power from the Avance and communicates measured values to the Avance for display on the system display unit.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in the Avance Anesthesia System. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The 7900 ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well as measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. The user interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices. Ventilator modes for the device include Volume Mode, Pressure Control Mode, Pressure Support with Apnea Backup Mode (Optional), Synchronized Intermittent Mandatory Ventilation (SIMV) Mode (Optional), Pressure Controlled Ventilation with Volume Guarantee (PCV-VG), and Volume Control Ventilation Mode for Cardiac Bypass Mode. Ventilator parameters and measurements are displayed on the system display unit.

Several options enable the mounting of the Datex-Ohmeda S/5 Anesthesia Monitor (most recently cleared via K051400). An additional option allows the S/5 AM to be linked to the power supply of the Avance such that when the Avance is turned on, the S/5 AM is also turned on. Additional configurations allow for the mounting of various patient monitors on the top shelf of the Avance.

INTENDED USE as required by 807.92(a)(5)

The GE Datex-Ohmeda Avance Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The device is intended for volume or pressure control ventilation. The Avance is not suitable for use in a MRI environment.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The GE Datex-Ohmeda Avance has been updated from the predicate version (K071142). There have been no changes to the intended use or fundamental scientific technology.

The software for the Avance has been updated to introduce several new features. The changes to the software include:

- Alarm Improvements. Improvements are made to the alarms to reduce nuisance alarms. These changes are the same as have been implemented in Aisys 4.0 (K073707).
- User Configurations. Addition of more default configurations.
- Fresh gas flow look-ahead VCV tidal volume delivery is now compensated for immediately upon user adjustments to total fresh gas flow.
- Usability Improvements Waves/Pages. The system will have more screen configurability for waveforms and the numerics
- MAC Age. The mathematical calculation for MAC will now be able to be made accounting for the patient age. This is the same as is displayed on the S/5 Anesthesia Monitor (K030812, K051400).
- Agent usage estimation. Estimation of the volume of agent used during a case for the Tec vaporizers is now provided to indicate how much agent was used during a case.
- Preset ventilator settings based on patient weight for PCV-VG mode. The preset ventilator settings at the start of a case can now be based on patient weight for PCV-VG mode, similar to the way preset vent settings can be based on patient weight for VCV mode in the previous Avance.
- Auto exit PSVPro backup mode. The system will now automatically exit SIMV-PC vent mode upon recognition of spontaneous breathing and resume PSVPro™ when patient resumes spontaneous breathing (change was previously made manually).
- Calibrate flow sensors reminder. An informational alarm message will appear when the system is not in therapy between cases to remind the user to calibrate the flow sensors if flows sensors have not been calibrated for 24 hours. Currently the manuals give this instruction.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The GE Datex-Ohmeda Avance has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with the following standards has also been made to support safe use of the device in its intended environment.

Standard	Title
EN 740 :1998	Anesthesia Workstations and their components
EN 60601-1:1990	Medical Electrical Equipment Part 1: General Requirements for Safety Incorporates Corrigendum July 1994; Includes Amendments A1:1993, A11:1993, A12:1993, A2:1995, A13:1996, IEC 601-1:1998 + A2:1995 + Corrigendum 1995, Modified
EN 60601-1-1:2000	Medical Electrical Equipment - Medical Electrical Systems
EN 60601-1-2:2001	Medical Electrical Equipment - Electromagnetic Compatibility

IEC 60601-1-4:2000	Safety of Programmable Electronic Medical Systems
EN 475:1995	Electrically Generated Alarm Signals
EN 850:1997	Small Medical Gas Cylinders - Pin Indexed
EN 980:1997	Graphical Symbols
EN 1041:1998	Information to be supplied with medical devices
EN 1089-3:1997	Color coding for medical gases
ISO5356-1:1996	Conical Connectors
EN 1820:1997	Reservoir Bags
IEC 60601-2-13:1998	Particular requirements for the safety of anaesthetic workstations

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The modifications made to the GE Datex-Ohmeda Avance did not require clinical testing.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the GE Datex-Ohmeda Avance as compared to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
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Ms. Adrienne Lenz  
Regulatory Affairs Manager  
Datex-Ohmeda, Incorporated  
Life Support Solutions  
P.O. Box 7550  
3030 Ohmeda Drive  
Madison, Wisconsin 53707

AUG 29 2008

Re: K081844

Trade/Device Name: GE Datex-Ohmeda Avance Anesthesia System  
Regulation Number: 21 CFR 868.5160  
Regulation Name: Gas Machine for Anesthesia or Analgesia  
Regulatory Class: II  
Product Code: BSZ  
Dated: August 6, 2008  
Received: August 7, 2008

Dear Ms. Lenz:

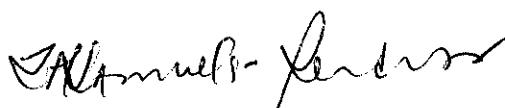
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

## Indications for Use

510(k) Number (if known): K 081844

Device Name: GE Datex-Ohmeda Avance Anesthesia System

Indications For Use:

The GE Datex-Ohmeda Avance Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The device is intended for volume or pressure control ventilation. The Avance is not suitable for use in a MRI environment.

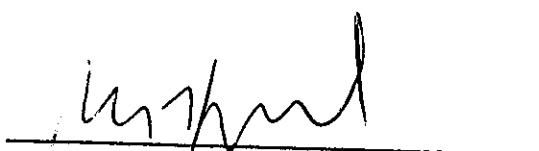
Prescription Use XXX AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K 081844